

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

SCIELE PHARMA, INC., <i>et al.</i> ,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 09-037 (RBK) (JS)
	)	(CONSOLIDATED)
LUPIN LTD., <i>et al.</i> ,	)	
	)	
Defendants.	)	
SHIONOGI INC., <i>et al.</i> ,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. NO. 10-135 (RBK) (JS)
	)	
MYLAN INC., <i>et al.</i> ,	)	
	)	
Defendants.	)	

**THE LUPIN DEFENDANTS' MEMORANDUM OF LAW  
IN OPPOSITION TO THE MOTION OF PLAINTIFF SHIONOGI PHARMA INC.  
FOR LEAVE TO FILE A SUR-REPLY**

OF COUNSEL:

BAYARD P.A.

Douglass C. Hochstetler  
Kelley Drye & Warren LLP  
333 West Wacker Drive  
Chicago, IL 60606

Richard D. Kirk (rk0922)  
Stephen B. Brauerman (sb4952)  
222 Delaware Avenue, 9<sup>th</sup> Floor  
P.O. box 25130  
Willmington, DE 19899-5130  
(302) 655-5000  
rkirk@bayardlaw.com  
sbrauerman@bayardlaw.com

Beth D. Jacob  
Kelley Drye & Warren LLP  
101 Park Avenue  
New York, NY 10178

Karen A. Confoy  
Erica S. Helms  
Sterns & Weinroth  
50 W. State Street, Ste. 1400  
Trenton, NJ 08607-1298

*Attorneys for Lupin Ltd. and Lupin  
Pharmaceuticals, Inc.*

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Defendants Lupin Ltd and Lupin Pharmaceuticals, Inc. (collectively “Lupin”) submit this memorandum in opposition to the motion (D.I. 302) of plaintiff Shionogi Pharma Inc. (“Shionogi”) for leave to file a sur-reply in opposition to Lupin’s motion to stay or modify the preliminary injunction entered December 6, 2011. Shionogi asserts that the purpose of its sur-reply is to address a supposedly new argument raised in Lupin’s reply and to add to an argument already briefed by both sides. In addition to those stated purposes, Lupin’s proposed sur-reply also includes improper arguments in footnotes addressed to points made in Lupin’s opening briefing.

Shionogi’s motion for a sur-reply should be denied. As this Court has ruled in rejecting sur-replies in another case, “the Court should not be assailed with dripping faucet briefing; that is, an endless trickle of briefs after motions are filed.” *Carlton v. Choicepoint, Inc.*, Civil No. 08-5779, 2009 WL 4127546, at \*4 n5 (D.N.J. Nov. 23, 2009) (admonishing parties not to make additional submissions after briefing was closed). Shionogi’s proposed sur-reply consists of “arguments originally made” or which could have been made, in its “opposition brief to Defendant’s motion, and fails to point to any exceptional circumstances warranting the filing of a sur-reply.” *Bell v. Lockheed Martin Corp.*, Civil No. 08–6292, 2011 WL 6256978, at \*1 n1 (D.N.J. Dec. 14, 2011) (denying leave to file sur-reply). In Delaware, as in New Jersey sur-reply briefs are appropriately denied when they do not respond to issues raised for the first time in a reply brief. *See In re Finova Group, Inc.*, C.A. No. 07-480-JJF, 2007 WL 3238764, at n.1 (D. Del. Oct. 31, 2007).

What Shionogi claims is new argument was made in Lupin’s *opening* memorandum, where Lupin argued that the Court erred in holding that it could not take into account the only test of Lupin’s product, which showed its  $T_{\max}$  was outside the range claimed in the patent. In

support of its argument, Lupin cited a Federal Circuit decision handed down the day before its motion was filed and described that holding as “vacating a preliminary injunction barring generic marketing in a Hatch-Waxman case because the district court had not held a hearing to resolve a ‘battle of experts.’” (D.I. 289, Lupin Op. Mem. at 9-10, discussing *Warner Chilcott Labs. Ireland Ltd. v. Mylan Pharms. Inc.*, No. 2011-1611, slip op. at 8-10 (Fed. Cir. Dec. 12, 2012) (non-precedential).) Lupin argued in its opening memorandum that Shionogi did not meet its obligation to present evidence that rebutted Lupin’s test results and showed that Lupin’s evidence of noninfringement lacked substantial merit. (Lupin Mem. at 9-10.) Shionogi failed to discuss this case or Lupin’s argument in its opposition memorandum, as Lupin pointed out in its reply. That is not an “exceptional circumstance warranting the filing of a sur-reply.” *Bell*, 2011 WL 6256978 at \*1 n1.

Shionogi’s proposed sur-reply also includes another point made in Lupin’s opening motion papers and ignored by Shionogi in its opposition – the FDA’s confirmation that Lupin was not permitted to change its package insert either to reflect test results of Lupin’s product or to state that the data on the label related to the brand product. Shionogi asserts that Lupin “offers no explanation” for not including this fact in earlier submissions. (Proposed sur-reply at 3, n.2.) But as stated in Lupin’s opening memorandum and the supporting Sands declaration, the approach to the FDA was made after the hearing, in reaction to the Court’s statements at the hearing that it doubted Lupin’s expressed belief and understanding of its obligation to include the brand’s data in its label. Since the conversations with the FDA had not taken place before the oral argument, they could not have been raised at that time. Shionogi’s second point is that the conversation was with “an unnamed person at the FDA,” but Leslie Sands states in her

declaration that she spoke with Martin Shimer and that his position with the FDA is Branch Chief for Regulatory. (Sands Decl. at ¶ 5.)

Shionogi's last two points are facially improper for a sur-reply brief. First, Shionogi concedes it is adding to an argument on burden of proof already briefed by the parties. Second, Shionogi complains in a footnote that Lupin moved for a stay in the Federal Circuit without waiting for this Court to act,<sup>1</sup> but such a motion is customary when a party moves for an expedited appeal. (Proposed Sur-reply at 3, n2.) Lupin's motions in the Federal Circuit were made two weeks after it moved in the district court to stay or modify the injunction.<sup>2</sup>

Shionogi's motion for leave to file a sur-reply should be denied. Lupin's motion for a stay or modification of the preliminary injunction should be granted, on the existing briefing.

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<sup>1</sup> A sur-reply in the district court is not an appropriate place for the parties to exchange arguments about statements made in briefing before the Federal Circuit. Lupin notes only that its criticism, as also expressed at the oral argument, was of plaintiff's counsel's improper argument and not of the Court's decision. If the Court wishes, Lupin would be pleased to forward to the Court copies of the Federal Circuit motion papers and briefs.

<sup>2</sup> Shionogi would not agree to an expedited appeal, although an appeal in the normal course would not have been heard for approximately one year, or at about the time estimated for the trial of this matter. For the Court's information: the Federal Circuit granted Lupin's motion for an expedited appeal over Shionogi's opposition. Lupin filed its opening brief on January 5. Shionogi's opposing brief is due within 21 days and Lupin's reply is due within seven days after service of the opposing brief. In addition, Shionogi's opposition to Lupin's motion to stay the preliminary injunction is due by 5 pm on January 9, and Lupin's reply is due January 13.

January 9, 2012

BAYARD P.A.

OF COUNSEL:

/s/ Richard D. Kirk (rk0922)

Douglass C. Hochstetler  
Kelley Drye & Warren LLP  
333 West Wacker Drive  
Chicago, IL 60606  
(312) 857-7070

Richard D. Kirk (rk0922)  
Stephen B. Brauerman (sb4952)  
222 Delaware Avenue, 9<sup>th</sup> Floor  
P.O. Box 25130  
Wilmington, DE 19899-5130  
(302) 655-5000  
rkirk@bayardlaw.com  
sbrauerman@bayardlaw.com

Beth D. Jacob  
Kelley Drye & Warren LLP  
101 Park Avenue  
New York, NY 10178  
(212) 808-7800

*Attorneys for Lupin Ltd. and Lupin  
Pharmaceuticals, Inc.*

Karen A. Confoy  
Erica S. Helms  
Sterns & Weinroth  
50 W. State Street, Ste. 1400  
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